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Introduction

Good morning Chairwoman DeLauro and members of the subcommittee. I am Dr. David Acheson, Assistant Commissioner for Food Protection at the Food and Drug Administration (FDA). I am pleased to be here today to discuss food safety and food imports from China.

FDA is committed to ensuring that America's food supply continues to be among the safest in the world. In recent years, we have done a great deal to protect the food supply from unintentional and deliberate contamination. Despite our progress in the areas of food safety and food defense, recent outbreaks of foodborne illness and the discovery of contaminated food and feed underscore the need to continually improve and adapt to a rapidly growing and changing global economy. Further, these events demonstrate the need to expand our risk based approach to product safety for imported products, expand the use of common information sharing mechanisms, such as the ITDS screening and tracking system maintained by the Bureau of Customs and Border Protection (CBP), and widen information gathering to improve the ability of CBP's National Targeting Center to focus FDA and CBP prevention and intervention efforts.

The President has engaged directly in the effort to make sure we are doing everything we can to protect Americans from unsafe imports. On July 18, he issued an Executive Order creating a Cabinet-level Working Group on Import Safety to promote the safety of imported products and tasked Secretary Leavitt with chairing the effort. On September 10, the Working Group issued its initial report, a Strategic Framework for addressing the problem, and the Working Group will publish a detailed Action Plan in mid-November. The Working

Group's efforts are about safety, not protectionism, and are directed at all imports, not those from any particular country.

Food Imports from China

Each year, approximately $2 trillion of imported products enter the United States. Experts project that import volume will triple by 2015. In the case of products that FDA regulates, between 2002 and 2006 total imports grew at an average annual rate of 16 percent per year, with foods for human consumption growing by 14 percent.

The United States imports food from many countries. For example, our neighbors in Canada and Mexico export a large volume of food to the United States. However, given the topic of today's hearing, I will focus my remarks on China.

China is one of the world's largest producers of agricultural products. China is a major supplier to the United States of seafood, canned vegetables, fruit juices, honey, and a variety of processed foods. In recent years, we have seen a dramatic surge of imports from China. During the past five years, FDA-regulated food imports from China increased by more than 140 percent.

Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, also known as the Bioterrorism Act, FDA receives information about food imported from China and other exporting nations before it reaches U.S. ports. This advance notice helps FDA identify high-risk imported foods that may pose a significant health risk to Americans or foods that may be linked to terrorism.

FDA has a history of concern about exports of food from China. Although we have witnessed some improvement in product quality, some Chinese companies continue to export substandard food products to the United States.

To improve this situation, my colleagues and I at FDA and HHS are actively engaged in negotiating a comprehensive memorandum of agreement with China related to food and feed. We are also negotiating an agreement relating to medical products. Our goal is to identify and implement actions that will limit the risk of substandard food and feed products from entering the United States. We hope to sign the agreement in early December.

Clearly, the safety of food and other FDA-regulated products remains a concern for FDA, Congress, and consumers. Our experience with Chinese aquaculture products and the recent melamine incident serve as good examples of the problem and FDA's actions in absence of such an agreement.

Aquaculture Imports from China

China is the largest exporter of aquaculture products to the United States, and FDA maintains an active program to test imports of Chinese aquaculture products for illegal residues. Beginning in November 2001, FDA issued a series of import alerts because shipments of Chinese aquaculture products tested positive for antibiotic residues or other contaminants. Most recently, in 2005 FDA issued an import alert for Chinese shrimp due to illegal nitrofurans residues. In 2006, FDA issued an import alert for eel from China due to presence of malachite green residues.

Between October 2006 and April 2007, FDA repeatedly identified residues of unapproved drugs and food additives in seafood imported from China. The residues included malachite green, fluoroquinolones, nitofurans, and gentian violet. These compounds are often used to inhibit the growth of bacteria and fungus on seafood or to prevent parasites. However, FDA has not approved these products for use as drugs or food additives for use in farm-raised seafood in the United States.

Nitrofurans, malachite green, and gentian violet have been shown to be carcinogenic in animal studies. Fluoroquinolones in food animals may increase antibiotic resistance in human pathogens. FDA responded to the continued presence of residues by announcing a broad import alert on all farm-raised catfish, basa, shrimp, dace (related to carp), and eel from China. Under this alert, FDA can detain all of these aquaculture products at the border until the shipments are proven to be free of residues that prompted the alert. Although the levels of the drug residues in these food products are very low, FDA is concerned about long-term exposure and the possibility of antibiotic resistance.

Melamine and the Safety of Feed and Pet Food Ingredients

On March 15, 2007, FDA learned that certain pet foods were sickening and killing cats and dogs. FDA found melamine and melamine analogues contaminants in wheat gluten imported into the U.S. from China. The wheat gluten was used as ingredients in pet food. FDA traced the suspect wheat gluten to a single supplier in China, Xuzhou Anying Biologic Technology. Once we identified the contaminant, FDA promptly issued an import alert focused on this supplier and began sampling 100 percent of all wheat gluten from China.

On April 16, 2007, FDA also launched an investigation of imported shipments of rice protein concentrate from China that also contained melamine and melamine analogues. FDA traced the suspect product to another supplier in China, Binzhou Futian Biologic Technology. FDA added this supplier to the import alert related to wheat gluten and began sampling 100 percent of all rice protein concentrate from China. On April 19, 2007, the FDA was notified that contaminated corn gluten from the same supplier in China caused illness and death of pets in South Africa. Based on this and other information, FDA then initiated a countrywide import alert for all vegetable protein from China. As a result of this import alert, vegetable protein from China cannot enter U.S. commerce until the shipments are proven to be free of melamine or melamine analogs. This import alert is still in place.

Further investigation revealed that a portion of the melamine-tainted pet food was used to supplement swine and poultry feed on a small number of farms. FDA and the U.S. Department of Agriculture identified some animals that ate tainted feed were processed into human food. FDA subsequently learned that some of the contaminated wheat gluten was used to make fish feed. Due to the small amounts present and the small amounts that would be consumed in an average U.S. diet, government scientists determined that there is no significant risk to human health from consuming food from animals that ate tainted feed.

Protecting American Consumers Every Step of the Way

The Interagency Working Group on Import Safety that the President formed to review our import safety procedures conducted a comprehensive review of current import safety practices for foods, drugs, and other consumer products.

Secretary Leavitt, the Chair of the Working Group, and Commissioner von Eschenbach traveled extensively throughout the United States during the past few months visiting ports of entry and FDA field operations. The insights that they gained during reviewing field operations helped shape the Strategic Framework document and will certainly help shape the recommendations in the forthcoming Action Plan.

The report that the Working Group issued, *Protecting American Consumers Every Step of the Way: A strategic framework for continual improvement in import safety*, outlines a recommended Framework for improving the safety of imported foods and other consumer products. The report identifies roles for the public and private sectors to continually improve our import safety system in a rapidly growing and changing global economy.

The working group has an aggressive schedule for public comment and follow-up. On October 1, the Working Group will conduct a public meeting in USDA's Jefferson Auditorium on public and private actions to promote the safety of imports. By mid-November, the Working Group will provide an Action Plan to the President. The Action Plan will reflect the public comments and recommend specific actions that the federal government and stakeholders can take to enhance import safety on all levels. The Action Plan will be based on the Strategic Framework announced on September 10 and will lay out a road map with short- and long-term recommendations for improving import safety.

The Strategic Framework recognizes that we must find new ways to protect American consumers and continually improve the safety of imports. The report recommends working

with the importing community to develop approaches that consider risks over the life cycle of an imported product and that focus actions and resources to minimize the likelihood of unsafe products reaching consumers. A risk-based, prevention-focused model will help ensure that safety is built into products before they reach our borders.

Supporting the Working Group model are six building blocks: 1) advance a common vision, 2) increase accountability, enforcement and deterrence, 3) focus on risks over the life cycle of an imported product, 4) build interoperable systems, 5) foster a culture of collaboration, and 6) promote technological innovation and new science.

Although the November Action Plan will bring forth more detailed actions, the Working Group released an Immediate Actions paper with the Strategic Framework. Federal agencies have already begun to implement these immediate high-priority Working Group recommendations. One of the key Immediate Actions is to accelerate interoperability of import data systems, which is an essential component of import safety. By November 12, federal agencies (including FDA) that rely on IT systems to review imported cargo must develop specific implementation plans, including necessary budgetary resources to achieve, by 2009, interoperability with the International Trade Data System managed by the U.S. Customs and Border Protection. This data processing system is called the Automated Commercial Environment, or ACE. This action is consistent with the Security and Accountability for Every (SAFE) Port Act of 2006, which requires all federal agencies that license, permit, or certify imported products to participate in the International Trade Data System, a single-window system for reporting on imports electronically.

Strategic Framework for Import Safety: Prevention, Intervention, Response

The September 10 Working Group report identified three organizing principles that serve as the strategic framework for import safety: prevention, intervention, and response. These three principles are consistent with FDA's life-cycle approach to food and feed safety.

At FDA, prevention, intervention, and response represent a strategic framework for the safety of food and feed imports as well as the safety of processed foods produced within our borders. Moreover, they serve as a framework for not only food safety, but also food defense.

Prevention is the cornerstone of an effective, proactive food defense and food safety strategy. The implementation of preventive control measures by industry is essential to prevent intentional or unintentional contamination of the food supply. In the prevention arm of FDA's strategy, FDA will develop scientific and analytical tools to better identify and understand risks and the effectiveness of control measures used to protect the food supply.

Risk-based *intervention* supplements the prevention arm of FDA's strategy. Intervention includes monitoring the success of, and identifying weaknesses in, preventive measures. Intervention augments prevention through inspection and sampling techniques that use modern detection technology. Intervention relies on information technology systems to improve FDA's ability to target and conduct inspection and surveillance, perform laboratory analysis, and achieve reliable 24/7 operations.

The *response* arm of the FDA strategy reduces the time between detecting and containing foodborne illness. FDA's recent experience with spinach and leafy greens, melamine, peanut

butter, and other contaminated products demonstrates the need for more effective response strategies. FDA must respond faster, communicate more effectively to consumers and FDA food safety partners, and limit economic hardship to the affected industries. FDA must also further integrate response systems with state, local, federal, and international agencies.

Using these three principles, FDA is designing a food safety strategy that better protects the American public and the U.S. economy from food safety and food defense threats.

Conclusion

We recognize that it is not possible to eliminate all risk associated with imports. Nor is it possible to eliminate all risk from food produced in the United States. However, we are engaged in a concerted effort with domestic and international partners – in government and industry – to develop and implement new ways to protect Americans and improve the safety of domestic and imported food.

I know that the Chairwoman and members of the subcommittee care very deeply about the safety of the food supply and the health of all Americans. America has one of the safest food supplies in the world, yet there is room for improvement. I am leading the effort at FDA to develop and implement a new strategy to protect America's food supply. I will continue to update the subcommittee on the progress of our plan, and I look forward to working with you to make our strategy a success.